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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,591	08/13/2001	Tomoyasu Sugiyama		7048
7590	02/27/2004		EXAMINER	
			SISSON, BRADLEY L	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/831,591	SUGIYAMA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-5, 11, 13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-5, 11, 13 and 14 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. <u>02232004</u> .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

**DETAILED ACTION**

*Supplemental Office Action*

1. On January 14<sup>th</sup>, 2004 an interview Summary was mailed to Applicant wherein it was indicated that the prior Office action contained a typographical error in the spelling of Mills et al., a prior art document made of record. While applicant had requested clarification of the number and identify of the cited prior art, no request for restarting of the period for response was made.
2. On February 19, 2003 applicant's representative left a voice-mail message for the examiner requesting that the period for response be restarted. During a telephonic interview of February 23, 2004 applicant's representative made indications that he had contacted the Office over the issue of correctly identifying the cited prior art back in November and December 2003 when the examiner was out of the Office and had spoken with SPE Gary Benzion, Ph.D. Applicant's representative also requested that the period for response be restarted to the full three months as the Office action of November 4<sup>th</sup>, 2003 contained errors or was otherwise defective as a consequence of the misspelling of Mills et al.
3. The procedure for determining if and to what extent a period for response is restarted is set forth in MPEP 710.06.

### **710.06 Situations When Reply Period Is Reset or Restarted**

Where the citation of a reference is incorrect or an Office action contains some other defect and this error is called to the attention of the Office within 1 month of the mail date of the action, the Office will restart the previously set period for reply to run from the date the error is corrected, if requested to do so by applicant. If the error is brought to the attention of the Office within the period for reply set in the Office action but more than 1 month after the date of the Office action, the Office will set a new period for reply, if requested to do so by the applicant, to substantially equal the time remaining in the reply period. For example, if the error is brought to the attention of the Office 5 weeks after mailing the action, then the Office would set a new 2-month period for reply. The new period for reply must be at least 1 month and would run from the date the error is corrected. See MPEP § 707.05(g) for the manner of correcting the record where there has been an erroneous citation.

Where for any reason it becomes necessary to remail any action (MPEP § 707.13), the action should be correspondingly redated, as it is the remailing date that establishes the beginning of the period for reply. *Ex parte Gourtaff*, 1924 C.D. 153, 329 O.G. 536 (Comm'r Pat. 1924).

A supplementary action after a rejection explaining the references more explicitly or giving the reasons more fully, even though no further references are cited, establishes a new date from which the statutory period runs.

If the error in citation or other defective Office action is called to the attention of the Office after the expiration of the period for reply, the period will not be restarted and any appropriate extension fee will be required to render a reply timely. The Office letter correcting the error will note that the time period for reply remains as set forth in the previous Office action.

4. The record clearly shows that Applicant brought the error to the attention of the Office while the current period for response was running, however, the request for restarting the period of response was not made until the third month of the response period. As set forth in MPEP 710.06, if the period for response is restarted, the period must be at a minimum of 1 month. Accordingly, with the request for restarting of the period to reply not occurring until with the

original third month of the reply period, the period for response is reset to expire one month from the mailing date of the instant Office action.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-5 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Mills et al.

*(Proceedings of the National Academy of Sciences, US, May 1979, Vol. 76, No. 8, pages 2232-2235).*

7. It is noted that the publication of Mills et al., is newly cited prior art. It is also noted that this newly cited prior art was known to applicant prior to filing (see page 3, lines 2 1-22, of the specification) yet not disclosed to the Office in an Information Disclosure Statement. Applicant is reminded of their "acknowledged duty. . ." as set forth in their signed "Combined Declaration and Power of Attorney."

*I acknowledge the duty to disclose all information I know to be material to patentability in accordance with Title 37, Code of Federal Regulations, §1.56.*

8. Claims 1-5 and 13 are all drawn to "a hybridization probe." For convenience, a claim 1 (amended) is reproduced below.

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1. (Amended) A hybridization probe that comprises a DNA capable of specifically hybridizing to a target nucleotide sequence, and an additional nucleotide sequence comprising one or more nucleotides selected from the group consisting of labeled nucleotides, labeled nucleotide derivatives, unlabeled nucleotides, and unlabeled nucleotide derivatives, wherein the additional in which a nucleotide sequence comprising labeled nucleotides or nucleotide derivatives is added to a DNA to be labeled, the added nucleotide sequence

a) comprises at least one nucleotide or nucleotide derivative comprising nucleotides and/or nucleotide derivatives having weaker affinity of hydrogen bonding in base pairing with bases of the target nucleotide sequence when compared with that those of hydrogen bonding in an a/t pair, in an a/u pair, and in a g/c pair;

b) comprises either or both of at least one labeled nucleotide and labeled nucleotide derivative; and

c) is b)-being introduced into the DNA to be labeled through nucleotide-adding reaction with terminal transferase.

9. As seen above, the claim recites the limitation that the "nucleotide derivatives" are added via the action of a "terminal transferase." Accordingly, the claim, for purposes of examination, has been interpreted as a product-by-process claim. Attention is directed to MPEP 2113 (R-1), reproduced below.

**2113 [R-1] Product-by-Process Claims****PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS**

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added,

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but is instead produced *in-situ* does not change the end product.).

10. Mills et al., page 22, left column, last two paragraphs, discloses production of PCR amplicons that comprise both normal dNTPs as well as derivatives thereof, wherein said nucleotide derivatives comprise inosinic acids as well as labeled nucleotides.

11. While applicant defines their product as a "hybridization probe," such speaks to intended use and does not speak to there being a material difference between the nucleic acid being claimed (a.k.a. a hybridization probe) and that disclosed in the prior art (an amplicon produced through polymerase chain reaction (PCR)). Accordingly, the amplicons produced by Mills et al., are considered to meet the structural requirements of the ("hybridization probe" claimed instantly, and as such, claims 1-5 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Mills et al.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over

16. Chenchik et al., (US Patent 5,565,340) in view of Mills et al.

17. Chenchik et al., column 11, disclose kits that comprise reagents used in performing PCR, and that the kits may also comprise added reagents, including terminal transferase.

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18. Chenchik et al., do not teach explicitly of including inosinic acids.
19. Mills et al. discloses performing PCR with inosinic acids.
20. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included inosinic acids in the kit of Chenchik et al., as Mills et al., teaches explicitly of using inosinic acids in PCK and the kit disclosed by Chenchik et al., is to comprise those very reagents that are used in performing PCR. In view of the detailed teachings, the ordinary artisan would have been both amply motivated and would have had a most reasonable expectation of success.
21. Accordingly, and in the absence of convincing evidence to the contrary, claims 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chenchik et al. (US Patent 5,565,340) in view of Mills et al.

### *Conclusion*

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.
23. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.
24. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson  
Primary Examiner  
Art Unit 1634

BLS  
24 February 2004